

REMARKS/ARGUMENTS

Claims 15, 17-18m and 20-24 are currently pending. Reconsideration of the rejections and passage to allowance are requested.

Rejections Under 35 U.S.C. § 112

The examiner has rejected claims 15-24 under 35 USC §112 first paragraph, alleging that the specification does not reasonably provide enablement for treating a proliferative disease in a mammal or human. The rejection is respectfully traversed.

It is well established that if *in vitro* tests correlate to a claimed method of invention, it constitutes a working example sufficient to provide enablement of the claims. See, e.g., MPEP 2164.02. This is particularly the case in instances where the state of the art recognizes such a correlation. In the present case, the compounds of the invention were shown to have activity in binding the BIR3 peptide binding pocket. Such activity has been shown to have a correlation to promoting apoptosis, which in turn has been shown to be a therapeutic method of treating proliferative disease. See, e.g., Kipp et al, "Molecular Targeting of Inhibitor of Apoptosis Proteins Based on Small Molecule Mimics of Natural Binding Partners," *Biochemistry*, Vol. 41(23), pp 7344-7349 (2002); and Arnt et al., "Synthetic Smac/DIABLO peptides enhance the effects of chemotherapeutic agents by binding XIAP and cIAP1 in Situ," *Journal of Biological Chemistry*, Vol. 277 (46), pp. 44236-44243 (2002); both cited in the present IDS. There is therefore a clear corollary recognized in the art between the activity demonstrated in the specification and the resulting potential as a therapeutic against proliferative disease.

The Examiner further states that, "proliferative disease encompass numerous and unrelated diseases, such as psoriasis and cancer. It is not understood how the administration of the compounds could embrace the treatment of such a large genus of diseases. It is for this that the rejection is maintained." See Office Action, page 3, first paragraph.

This is not the proper standard of enablement. A method of treatment is not being claimed. Where a composition of matter is claimed, the claimed subject matter does not have to provide enablement for a medicament to treat all of the diseases encompassed within proliferative diseases. It is only necessary to determine whether one of skill in the art is enabled to make and use the entire scope of the claimed invention without undue experimentation. See MPEP 2164.08. It is only necessary that the specification enables the claimed composition to treat a proliferative disease.

In the present case, the claims are directed to a composition of matter. There is no question as to whether the specification enables the claimed compound. Withdrawal and reconsideration of the rejection is required.

The examiner has also rejected claims 15-24 under 35 U.S.C §112 first paragraph, as failing to comply with the written description requirement. In particular the examiner states, "if a biomolecule is described only by a functional characteristic without any disclosed correlation between function and structure of the sequence, it is 'not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence'." (Page 12 of the Office Action).

The rejection is improper, but applicants have amended the claims to remove the phrase, and thus facilitate issuance of the patent. Withdrawal of the rejection is respectfully requested.

Rejection Under 35 USC 102

The Examiner has rejected claims 15, 17, 18, and 20-24 under 35 USC 102 as being anticipated by U.S. Patent No. 6,576,609 to Soff. Applicants have amended the claims, and the rejection is traversed. Withdrawal is requested.

Double Patenting Rejection

Applicants acknowledge the provisional rejection based upon of non-statutory obviousness-type double patenting. Applicants also acknowledge that if all other rejections are traversed, this rejection should be withdrawn, as the present application has an earlier filing date than U.S. application No. 10/519,042. This application is application serial No. 10/519,042, and thus cannot serve as a basis for a double patenting rejection. Accordingly, withdrawal of the rejection is respectfully requested.

The application is considered to be in condition for allowance and such action is solicited.

Respectfully submitted,



Mark E. Baron
Attorney for Applicants
Reg. No. 46,150

Novartis Institutes for BioMedical Research Inc.
Patent Department
400 Technology Square
Cambridge, MA 02139
(617) 871-7347
Date: August 14, 2008